4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-Z-0025]

Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services (Department or HHS) is announcing the withdrawal of a notice published in the *Federal Register* on January 21, 2021, entitled "Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation." HHS also withdraws the requests for proposals issued on its website on September 24, 2020, and revised on January 13, 2021, and ends the period for submission of proposals in response to the requests for proposals.

DATES: The notice published in the Federal Register on January 21, 2021, at 86 FR 6343, is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993, 301-796-1054.

SUPPLEMENTARY INFORMATION: On September 24, 2020, HHS issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs (collectively, the RFPs) and posted related "Frequently Asked Questions" documents (FAQs) on its website. On January 21, 2021, HHS published a notice in the *Federal Register* entitled "Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation" (the HHS Notice) (86 FR 6343). The HHS Notice referred to revised versions of the RFPs. The

responses to the RFPs were directed in the HHS Notice and in the RFP for Personal Prescription Drug Importation issued on September 24, 2020, and revised on January 13, 2021, to be submitted to an HHS email address: import@hhs.gov, while the RFP for Insulin Reimportation Programs issued on September 24, 2020, and revised on January 13, 2021, directed that responses be sent to import@hhs.gov and to the Director of the FDA Import Division in the region of the intended port of entry. The Department is not aware that any proposals were received in response to the HHS Notice or RFPs. The HHS Notice, RFPs, and FAQs are withdrawn. All website statements and other informal issuances with respect to the HHS Notice and RFPs are also withdrawn. Accordingly, no proposals submitted to HHS or FDA in response to the HHS Notice or RFPs on or after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered by HHS or FDA. HHS intends to consider alternatives to the RFPs.

Dated: <u>June 11, 2021</u>.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: June 28, 2021.

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Xavier Becerra,

Secretary, Department of Health and Human Services.

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